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STATUS OF CLAIMS:

Claims 1-4, 7-22 and 28-46 are presently pending.

Withdrawn claims 23-27, which correspond to non-elected Groups IV and V are canceled above without prejudice or disclaimer. Withdrawn claims 15-22 and 28-32, however, are not canceled at this time as they will be entitled to consideration in the event of the allowance of the generic claim upon which they are based as provided by MPEP 809.02(a).

Claims 1, 3, 4, 7, 17-22 and 29-31 are amended above.

Support for the amendment of claim 1 can be found, for example, in original claim 3 and in the specification at page 20, lines 25-35.

Support for the amendment of claim 3 can be found, for example, in original claim 4.

Support for the amendment of claim 4 can be found, for example, in original claim 3.

Support for the amendment of claims 17-22 and 29-31 can be found, for example, in the specification at page 20, lines 25-35 and Example 1.

Support for new claims 33-46 can be found in original claims 1-32 (see, in particular, claims 1-10, 14, 17 and 21).

Hence, no new matter is added.

REMARKS:

A. Rejection of Claims 1-4, 7, and 8-14

Claims 1-4, 7, and 8-14 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. WO 94/20070 (Duncan). Applicant respectfully traverses this rejection and its supporting remarks.

Claim 1 is presently directed to a composition adapted for intranasal delivery that comprises the following: (a) at least one bioadhesive, which is a cross-linked derivative of poly(acrylic acid), (b) at least one adjuvant, and (c) at least one antigen.

To anticipate a claim, a single source must contain all of the elements of the claim. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984); *In re Marshall*, 578 F.2d 301, 304, 198 U.S.P.Q. 344, 346 (C.C.P.A. 1978). Moreover, the single source must disclose all of the claimed elements

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arranged as in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989); *Connell v. Sears Roebuck & Co.*, 722 F.2d 1542, 1548, 220 U.S.P.Q. 193, 198 (Fed. Cir. 1983).

Duncan, while describing various components of claim 1, does not contain a description of the elements of claim 1 arranged as presently claimed, i.e., (a) at least one bioadhesive, which is a cross-linked derivative of poly(acrylic acid), (b) at least one adjuvant, and (c) at least one antigen, all combined within a composition that is adapted for intranasal delivery.

For at least these reasons, claim 1 is not anticipated by Duncan. Claims 2-4, 7-22 and 28-32, which depend from claim 1, are not anticipated by Duncan for at least the same reasons.

(New claims 33-46 are not anticipated by Duncan, at least because this reference does not teach the use of a detoxified mutant of bacterial ADP-ribosylating toxin as an adjuvant.)

For at least these reasons, reconsideration and withdrawal of the outstanding rejection of claims 1-4, 7, and 8-14 under 35 U.S.C. 102(a) as being anticipated by Duncan are respectfully requested.

B. Rejection of Claims 1, 7 and 8 under 35 U.S.C. 103(a)

Claims 1, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duncan in view of Giuliani et al. Applicant respectfully traverses this rejection and its supporting remarks.

Regarding Duncan, it is noted that greater than expected results are evidence of nonobviousness. M.P.E.P. 716.02(a).

"A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness ... of the claims at issue." *In re Corkill*, 711 F.2d 1496, 226 USPQ 1005 (Fed. Cir. 1985). In *Corkill*, ***the claimed combination showed an additive result when a diminished result would have been expected.*** This result was persuasive of nonobviousness even though the result was equal to that of one component alone....

Id. (Emphasis added.)

In this regard, Example 2 of Duncan reports that, for an influenza antigen administered orally in combination with a bioadhesive, the cellulose polymer yielded antibody titers that were *greater than* the titers associated with the cross-linked poly(acrylic acid) polymers, in particular, 4-8 times the titers associated with the carbopol after 28 days, and 2-4 times the titers associated with polycarbophil after 28 days.

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Example 1 of the present specification presents geometric mean antibody titers \pm standard error for an influenza antigen administered intranasally in combination with a bioadhesive. With reference now to Table 1, it can be seen that the geometric mean antibody titers reported for the cellulose polymer were less than the geometric mean antibody titers reported for the cross-linked poly(acrylic acid) polymers, in particular, 1/5 of the geometric mean antibody titers reported for the carbopol after 28 days, and 1/2 of the geometric mean antibody titers reported for polycarbophil after 28 days.

Hence, analogous to *In re Corkill* above, the claimed combination of antigen and cross-linked poly(acrylic acid) derivative, when delivered intranasally, indicated an additive result, when a diminished result would have been expected in view of Duncan.

For at least these reasons, it is submitted that claim 1 is unobvious in view of Duncan.

Giuliani et al., which is cited for its disclosure concerning *E. coli* modified endotoxin LT-R72, does not make up for the above deficiencies in Duncan.

For at least these reasons, it is respectfully submitted that independent claim 1 is unobvious over Duncan in view of Giuliani et al.

Claims 2-4, 7-22 and 28-32, which depend from claim 1, are unobvious over Duncan in view of Giuliani et al. for at least the same reasons.

(New claims 33-46 are not are unobvious over Duncan in view of Giuliani et al., at least because these references do not teach or suggest the use of a detoxified mutant of bacterial ADP-ribosylating toxin as an adjuvant.)

Accordingly, reconsideration and withdrawal of the outstanding rejection of claims 1, 7 and 8 under 35 U.S.C. 103(a) as being unpatentable over Duncan in view of Giuliani et al. are respectfully requested.

CONCLUSION

Applicant submits that the claims of the present invention are in condition for allowance, early notification of which is earnestly solicited.

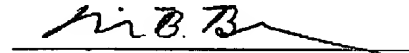
Should the Examiner be of the view that an interview would expedite consideration of the application, request is made that the Examiner telephone the Applicant's attorney at (703) 433-0510 in order that any outstanding issues be resolved.

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The Office is authorized to charge any fees required, to deposit account number 50-1047.

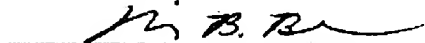
Respectfully submitted,



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<p>I hereby certify that this correspondence is being deposited with the United States Patent and Trademark Office on <u>May 28, 2004</u> via facsimile to: 703-872-9306.</p> <p><u>David B. Bonham</u> (Printed Name of Person Mailing Correspondence)</p> <p> (Signature)</p>
